

CLAIMS

1. A substantially pure polypeptide, which comprises at least one amino acid sequence selected from the group consisting of:

5 (a) an amino acid sequence selected from Rv2653c, Rv2654c or RD1-ORF5;

(b) an immunogenic portion of any one of the sequences in (a); and

(c) an amino acid sequence analogue having at least 70% sequence identity to any one of the sequences in (a) or (b) and at the same time being immunogenic.

10 2. A substantially pure polypeptide according to claim 1, wherein the amino acid sequence analogue has at least 80% sequence identity to any of the sequences in (a) or (b).

3. A fusion polypeptide, which comprises at least one amino acid sequence according to claim 1 and at least one fusion partner.

15 4. A fusion polypeptide according to claim 3, wherein the fusion partner comprises a polypeptide fragment selected from the group consisting of:

(a) a polypeptide fragment derived from a virulent mycobacterium;

(b) a polypeptide according to claim 1; and

20 (c) at least one immunogenic portion of any of such polypeptides in (a) or (b).

5. A polypeptide, which comprises at least one amino acid sequence according to claim 1 which is lipidated so as to allow a self-adjuvanting effect of the polypeptide.

25 6. An immunogenic composition comprising at least one polypeptide according to claim 1.

7. An immunogenic composition according to claim 6, which is in the form of a vaccine.

8. An immunogenic composition according to claim 6, which is in the form of a skin test

30 reagent.

9. A nucleic acid fragment in isolated form which

(a) comprises at least one nucleic acid sequence which encodes a polypeptide as defined in claim 1, or comprises a nucleic acid sequence complementary thereto;

35 and/or

(b) has a length of at least 10 nucleotides and hybridizes under stringent hybridization conditions with a nucleotide sequence selected from Rv2653c, Rv2654c or RD1-ORF5, or a nucleotide sequence complementary to any one of these sequences; or with a nucleotide sequence selected from a sequence in (a).

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10. A nucleic acid fragment according to claim 9, which is a DNA fragment.

11. A replicable expression vector, which comprises at least one nucleic acid fragment according to claim 9.

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12. A transformed cell harbouring at least one vector according to claim 11.

13. A method for producing a polypeptide according to claim 1, comprising:

(a) inserting a nucleic acid fragment according to claim 12 into a vector which is able to replicate in a host cell, introducing the resulting recombinant vector into the host cell, culturing the host cell in a culture medium under conditions sufficient to effect expression of the polypeptide, and recovering the polypeptide from the host cell or culture medium;

(b) isolating the polypeptide from a whole mycobacterium from culture filtrate or from lysates or fractions thereof; or

(c) synthesizing the polypeptide.

14. A method of diagnosing tuberculosis caused by virulent mycobacteria in an animal, including a human being, comprising intradermally injecting, in the animal, at least one polypeptide according to claim 1 or an immunogenic composition according to claim 6, a positive skin response at the location of injection being indicative of the animal having tuberculosis, and a negative skin response at the location of injection being indicative of the animal not having tuberculosis.

30 15. A method for immunising an animal, including a human being, against tuberculosis caused by virulent mycobacteria comprising administering to the animal at least one polypeptide according to claim 1 or an immunogenic composition according to claim 6.

35 16. A monoclonal or polyclonal antibody, which is specifically reacting with a polypeptide according to claim 1 in an immuno assay, or a specific binding fragment of said antibody.

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17. A pharmaceutical composition which comprises an immunologically responsive amount of at least one member selected from the group consisting of:

- (a) a polypeptide selected from Rv2653c, Rv2654c or RD1-ORF5, or an immunogenic portion thereof;
- (b) an amino acid sequence which has a sequence identity of at least 70% to any one of said polypeptides in (a) and is immunogenic;
- (c) a fusion polypeptide comprising at least one polypeptide or amino acid sequence according to (a) or (b) and at least one fusion partner;
- (d) a nucleic acid sequence which encodes a polypeptide or amino acid sequence according to (a), (b) or (c);
- (e) a nucleic acid sequence which is complementary to a sequence according to (d);
- (f) a nucleic acid sequence which has a length of at least 10 nucleotides and which hybridizes under stringent conditions with a nucleic acid sequence according to (d) or (e); and
- (g) a non-pathogenic micro-organism which has incorporated therein a nucleic acid sequence according to (d), (e) or (f) in a manner to permit expression of a polypeptide encoded thereby.